

REMARKS

Claims 1-38 have been canceled without prejudice or disclaimer as to the subject matter that they contain. Claims 39-56 have been added and are currently pending.

It is respectfully submitted that new claims 39-56 are fully supported by the originally filed application. For example, claim 39 recites subject matter disclosed on page 3, beginning at line 15 and on page 6, Table 3, where Applicant discloses example formulations including the addition of water in the range of 15-79% of the total mixture. Claims 40 and 41 find support from at least original claims 30, 15 and 21. Claims 42-43 find support throughout the specification and Tables. Claim 44 finds support from original claims 2, 3, 6 and in the Tables of the specification. Claims 45-46 find support from original claim 11, 13, 20 and at least on page 9, lines 15-16 of the specification. Claims 47-48 recite subject matter disclosed on page 3, beginning at line 15 and in Table 2, where Applicant discloses an example formulation including only two excipients. Original claim 9 discloses the range of ribavirin in a mixture.

Support for claims 49-53 should be apparent from the specification and the discussion above. In addition, claims 51 and 53 find support from the abstract where Applicant discloses preparing pharmaceutical dosages of ribavirin mixtures. Claims 54-56 also find support throughout the specification, including on page 1, beginning at line 21 and page 3, beginning at line 15, where Applicant describes the advantages of formulating a ribavirin mixture by wet granulation. Applicant teaches that such a process achieves better flow characteristics enabling faster encapsulation with lower weight variations.

Accordingly, it is respectfully submitted that new claims 39-56 are fully supported by the originally filed application and their entry would not raise new matter issues. Entry of the new claims are respectfully solicited.

The specification has been amended to correct a typographical error. In particular, U.S. Patent No. "5,196,594" was rewritten as "5,916,594", the former having incorrectly transposed the two digits "19" in the number. U.S. Patent No. 5,916,594 is being submitted in an Information Disclosure Statement (IDS) together with this Preliminary Amendment.

One sheet of Formal Drawings has been attached to the present paper. Its entry is respectfully solicited.

Furthermore, it is respectfully submitted that the pending claims in the application are patentable over the art cited in Applicant's IDS. The pending process claims relate to combining ribavirin with a wetting agent. The pending composition claims consist essentially of free flowing ribavirin particles.

As noted in the specification, there are processing difficulties in preparing ribavirin compositions. These difficulties are also recognized in the art. For example, see U.S. Patent No. 5,914,128 to Liebowitz at column 1, beginning at line 15. To solve these problems, Liebowitz teaches a process using "dry" compaction. (See, e.g., column 1, lines 30-34.) Given the problems associated with ribavirin formulations, as identified by Liebowitz and others, it is respectfully submitted that one of skill in the art would be motivated to follow the dry compacting process of Liebowitz. Hence, it is respectfully submitted that the prior art would not have lead one of skill in the art to a process of

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preparing a ribavirin composition, with a likelihood of success, by a wet process or of achieving a free flowing ribavirin composition.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Daniel Bucca", with a long, sweeping horizontal line extending to the right.

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